

REMARKS

Claims 2, 4-8, 10-20 and 23 are pending in the application.

35 U.S.C. §112, Second Paragraph Rejection

Claims 2, 4-8, 10-20 and 23 stand rejected under 35 U.S.C. §112 as being indefinite. According to the Examiner, the application uses the terms "fractionating column" and "rectification column" interchangeably and that is not clear from the application that the terms are interchangeable since the application does not provide a definition for either term.

Patent applications are directed to those of ordinary skill in the art. Those of skill in the art understand that a fractionating column and a rectification column are alternative terms used to refer to the same type of equipment. As is evident from Knoer et al., U.S. 3,644,179 (Knoer), cited by the Examiner, a fractionating column employs rectifiers to separate fractions of the composition being distilled. See, for example, Knoer at Col. 4, lines 42-45. Such a column is also known as a rectification column because it employs rectifiers to separate fractions of the composition being distilled. Although applicants have used the terms interchangeably in the specification and believe that the claims are supported by the specification regardless of whether the claims recite a fractionating column or a rectification column, applicants have amended the claims to recite a rectification column, which corresponds with the terms used in Example 6. Applicants respectfully request withdrawal of the Examiner's §112 rejection.

35 U.S.C. §103(a) Rejection Based on Knoer et al. in view of Cosgrove, and further in view of Ghisalberti, Reaney and Saebo et al.

Claims 2, 4-6 and 23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Knoer in view of Cosgrove U.S. 5,194,640 ("Cosgrove"), and further in view Ghisalberti (WO2001/18161) ("Ghisalberti"), Reaney, U.S. 6,420,577 ("Reaney"), and Saebo et al., U.S. 6,410,761 ("Saebo").

According to the Office Action, Knoer discloses that it is known in the art to use a wiped film evaporator in combination with a fractionating column to distill compositions which are prone to react upon heating. Knoer discloses the use of a thin film evaporator in combination with a fractionating column to distill tall oil. Cosgrove is cited for disclosing that tall oil contains a mixture of fatty acids, including oleic and linoleic acids. Ghisalberti discloses a process for the preparation of conjugated linoleic acid (CLA), and further discloses that the CLA can be refined by conventional refining techniques in order to obtain high grade CLA. The Office Action asserts that it is known from Saebo and Reaney, that CLA undergoes thermal rearrangement at elevated temperatures, creating undesirable trans-trans isomers, and therefore distillation techniques that involve elevated temperatures are to be avoided.

According to the Office Action, the problem of distilling CLA to obtain a CLA enriched in desirable isomers is similar to the problem faced by Knoer in distilling tall oil since both materials contain substances that are prone to react upon heating. The Office Action asserts that it would have been obvious to utilize the thin film evaporator and fractionating column of Knoer to further distill CLA as disclosed by Ghisalberti,

since the Knoer apparatus is a known apparatus for distilling materials prone to react upon heating. Reconsideration of the Examiner's rejection in view of the following remarks is respectfully requested.

Knoer relates to a process for distilling crude tall oil, which is a mixture of rosin acids and fatty acids. Knoer discloses that the crude tall oil also contains several constituents that react with the rosin acids and fatty acids during prolonged contact under heating. These constituents include phenols and terpene alcohols in the light ends and wax alcohols in the heavy ends. Knoer discloses that improved yield and purity of the rosin acids and fatty acids can be achieved if the crude tall oil is first pretreated in a thin film evaporator and a rectifier to remove the light ends (phenols and terpenes) from the crude tall oil. Residence time in the evaporator is on the order of seconds, which is sufficient to remove as much as 70% of the reactive substances capable of reacting with the rosin and fatty acids. Knoer at Col. 3, lines 8-15. Then the residual tall oil is passed to an apparatus comprising a thin film evaporator and a fractionating column where the thin film evaporator serves to remove the majority of the heavy ends (wax alcohols). Knoer at Col. 3, lines 27-30. Accordingly, Knoer teaches that the majority of the substances prone to react at high temperatures (light ends and heavy ends) are removed from the tall oil before the residual tall oil mixture ever reaches the fractionating column. Fractionation to obtain the rosin acid and fatty acid products then proceeds at high temperature in the Knoer process after the majority of the reactive substances have been removed, thereby improving yield and quality of the rosin acid and fatty acid products.

The fact that the fatty acids in tall oil include linoleic acids and oleic acids and that Knoer discloses that tall oil can be distilled in a fractionating column to improve the yield of the fatty acids, including linoleic acid, is irrelevant to the problem of how to improve the yield of desirable CLA isomers. This is so because linoleic acids are heat stable at the temperatures required for distillation whereas conjugated linoleic acids are not. As demonstrated by a comparison of Examples 3 and 4 in Applicants' application, Example 3 shows that safflower oil methyl esters, containing non-conjugated linoleic methyl esters, are substantially heat stable, even when subjected to temperatures of 200°C for 50 hours, whereas Example 4 shows that conjugated linoleic acid esters undergo substantial rearrangement into undesirable isomers after only 77 minutes of exposure to 195°C temperatures. Thus, the disclosure in Knoer that tall oil can be distilled after removal of the light and heavy ends to improve the yield of non-conjugated fatty acids does not aid one of skill in the art seeking to improve the yield of desirable isomers of conjugated linoleic acids because the end products sought to be obtained have completely different thermal stabilities.

Further, in the presently claimed technology, there are no components in the CLA ester stream that react with the CLA esters, such as the phenols, terpenes and wax alcohols in tall oil. Rather it is the CLA esters that undergo thermal rearrangement at high temperatures into undesirable isomers. Thus, the problem of achieving a CLA ester stream that is enriched in desirable isomers and is decreased in undesirable isomers is completely different from the problem facing Knoer. In Knoer, the problem is how to remove reactive components that are known to react with the desirable end

product at the high temperatures needed for distilling the desirable end product. In the present case, the problem is how to remove temperature stable side products that are not reactive with the desired end product where the desired end product itself is not temperature stable. Because the problem of obtaining a CLA ester enriched in desirable isomers is not the same problem encountered in distilling crude tall oil, as suggested by the Office Action, it is submitted that it would not have been obvious to utilize a wiped film evaporator combined with a rectification column to distill a thermally sensitive CLA ester stream.

Ghisalberti discloses a process for preparing CLA by reacting a linoleic acid-containing oil with an excess of glycerol and an alkali metal hydroxide at temperatures of 200° C to 250° C. (Ghisalberti at page 5 lines 4-8.) The resulting CLA from the alkaline isomerization of linoleic acid is a complex mixture of CLA isomers, including a full range of 11,13, 9,11 and 10,12 CLA isomers. (Ghisalberti at page 8, lines 4-13.) The most abundant isomers include the c9, c11 and c10, c12 isomers, Id., neither of which are preferred isomers in accordance with the present application. Ghisalberti discloses that the resulting CLA mixture can optionally be refined to provide a purified, odorless and tasteless final CLA product using conventional techniques such as drying under a vacuum, clarification by bleaching earth, and stripping by vacuum distillation techniques. According to the Office Action, such conventional techniques would include the use of a wiped-film or thin film evaporator connected to a fractionating column as disclosed in Knoer. However, Ghisalberti is concerned with techniques for purifying an already obtained CLA product to remove minor impurities affecting odor and taste,

whereas Knoer is concerned with refining a crude oil product containing major reactive species. There is no indication in Ghisalberti that the obtained CLA product mixture contains any impurities that react with the CLA. Thus, there would be no motivation to utilize the apparatus disclosed in Knoer merely to remove impurities affecting the odor and taste of the Ghisalberti CLA.

Moreover, even if the teachings of Knoer were somehow combined with the teachings of Ghisalberti, the combination would still not teach or suggest the process claimed in the present claims. The present claims specify that it is an ester stream of conjugated linoleic acid esters that is distilled in the distillation apparatus. Ghisalberti, however, discloses a process for preparing CLA, not CLA esters, as presently claimed, and nowhere teaches or suggests the claimed step of distilling an ester stream containing conjugated linoleic acid esters. Conjugated linoleic acids have different properties than conjugated linoleic acid esters, such that the materials are not the same. Moreover, CLA esters are typically an intermediate in the CLA production process and must be further chemically treated in order to obtain a final CLA product. Ghisalberti, however, is concerned only with refining the final CLA product and there is certainly no teaching or suggestion in Ghisalberti of conducting Ghisalberti's optional refining process on a CLA ester intermediate, as specified in the present claims.

The citations to Saebo and Reaney merely confirm that CLA is not thermally stable and undergoes thermal rearrangement into undesirable isomers at high distillation temperatures. Saebo emphasizes that the advantage of distilling in a molecular distillation plant is the short time (less than one minute) at which the CLA is

held at an elevated temperature (Saebo at Col. 10, lines 27-31). Reaney discloses that distillation is not an appropriate method for refining CLA. In view of these teachings it would not have been obvious to one of skill in the art to couple a wiped-film or thin film evaporator (which is a type of molecular distillation) with a rectification column to refine CLA esters, as required by the present claims, since the addition of a rectification column necessarily increases the time that the CLA ester stream is exposed to an elevated temperature. The residence time of the CLA ester stream in the rectification column is on the order of 30 minutes, which is significantly greater than the less than one minute exposure to elevated temperatures disclosed by Saebo. Moreover, one would expect from the Saebo disclosure that increasing the time that the CLA ester stream is exposed to elevated temperatures would lead to the formation of undesirable isomers. A comparison of the results from Example 1 of the present application (thin film evaporator only as the distillation apparatus) with the results from Example 6 (thin film evaporator connected to a rectification column) shows that adding the rectification column actually increased the amount of desired CLA esters, as well as increased the product yield. See, March 13, 2009 Rongione Affidavit at ¶10. This result is surprising and unexpected given Saebo's emphasis on short exposure time to elevated temperatures and Reaney's disclosure that distillation is not an appropriate method for refining CLA.

It is therefore submitted that the proposed combination of Knoer, Cosgrove, Ghisalberty, Saebo and Reaney does not disclose or suggest the presently claimed distillation process wherein a CLA ester stream is distilled in a thin film or wiped-film

evaporator connected to a rectification column having a heater operated at a temperature in the range of 240° C to 270° C to obtain a CLA ester stream enriched in c9,t11, t10,c12 isomers.

35 U.S.C. §103(a) Rejection Based on Saebo in view of Baltes et al., Knoer, Cosgrove, Reaney, Kirk-Othmer and Sachtler

Claims 8 and 10-20 have been rejected as being unpatentable over Saebo in view of Knoer, Cosgrove, Reaney, Baltes et al. (U.S. 3,162,658) ("Baltes"), and Sachtler (U.S. 5,326,925) ("Sachtler"). According to the Office Action, Saebo discloses a process for producing CLA esters by an esterification process involving methanol, followed by an isomerization step. Knoer is cited as above for disclosing a wiped film evaporator in combination with a fractionating column for distilling tall oil, while Cosgrove is cited for disclosing that tall oil includes linoleic acid. Reaney is cited for disclosing that distillation is not an appropriate method for CLA. Baltes is cited for disclosing an alkali metal catalyst to catalyze the isomerization step, and Sachtler is cited for allegedly disclosing a dual reaction system in an isomerization process. Kirth-Othmer is cited for disclosing that sesame seed oil contains linoleic acid. According to the Office Action, it would have been obvious to utilize seed materials containing linoleic acid to produce a CLA material as suggested by Saebo, and modify the isomerization step as suggested by Baltes, using a dual reaction zone apparatus for the isomerization, as suggested by Sachtler. The resulting CLA ester stream could then be purified using the wiped film evaporator/fractionating column apparatus, as suggested by Knoer, since such equipment is useful for removing substances prone to react at

high temperatures and Saebo and Reaney disclose that CLA is sensitive to high temperatures. Reconsideration of the Examiner's rejection in view of the following remarks is respectfully requested.

The presently amended claims are directed to a process that achieves a CLA ester stream that is enriched in desired c9,t11, t10,c12 isomers of CLA esters. The resulting enriched CLA ester stream is obtained by distilling a first CLA ester stream in a distillation apparatus that combines a wiped-film or thin film evaporator and a rectification column having a heater operating at a temperature of 240° C to 270° C, to produce a second ester stream that is enriched in the desirable CLA isomers.

As pointed out above in connection with the rejection of claims 1, 2 and 4-7, neither Saebo, alone or in combination with Knoer, Cosgrove, and Reaney, suggest the use of a thin film or wiped-film evaporator connected to a fractionating column to distill a CLA ester stream to increase the amount of desirable c9,t11 and t10,c12 CLA isomers, as required by amended claim 8. In particular, Saebo discloses distilling a CLA product stream using molecular distillation and emphasizes the extremely short exposure time (less than one minute) to elevated temperatures that such a distillation system provides. Saebo provides no suggestion or motivation to one of skill in the art to couple the molecular distillation system to a rectification column, as specified in amended claim 8, since to do so would necessarily increase the exposure time to elevated temperatures, contrary to the teachings of Saebo. Reaney similarly teaches that distillation is not an appropriate method for purifying CLA.

As noted above, Knoer discloses a process for distilling tall oil wherein the majority of the substances prone to react at high temperatures (light and heavy ends) are removed from the crude tall oil through the use of a thin film evaporator before the residual tall oil reaches the fractionating column. The residual tall oil is then introduced into the fractionating column where it can be distilled into the desired rosin acid and fatty acid products, both of which are stable at high temperatures.

In the presently claimed technology, there are no components, such as light ends or heavy ends that react with the CLA esters. Rather it is the CLA esters that undergo thermal rearrangement at high temperatures resulting the formation of undesirable isomers.

Given that there are no components to be removed from the ester stream that are reactive with the CLA esters, and given the clear teaching from Saebo and Reaney that high temperature distillation is inappropriate for CLA since it is thermally unstable, it is submitted that it would not have been obvious to utilize a wiped film evaporator combined with a fractionator as disclosed by Knoer, since Knoer teaches that such equipment is utilized to remove temperature reactive components (that are non-existent in the presently claimed ester stream) before fractionation of the thermally stable rosin acids and fatty acids.

The Examiner's citation of Baltes and Sachtler in combination with Saebo, Knoer, and Reaney, does not satisfy the deficiencies noted above. Baltes relates to a process for preparing conjugated linoleic acids and does not mention or suggest any method of distilling conjugated linoleic acids. Sachtler is merely cited for disclosing a dual reaction

system and does not relate at all to a process for preparing and distilling a conjugated linoleic acid ester stream. Neither Baltes nor Sachtler discloses or suggests distilling an ester stream containing CLA esters using a wiped-film or thin film evaporator connected to a fractionating column to obtain an ester stream enriched in c9,t11 and t10,c12 CLA isomers, as required by amended claim 8 and the claims dependent thereon. Therefore, even if the references were combined as proposed in the Office Action, the combination does not disclose or suggest the process recited in claim 8.

For all of the above reasons, it is submitted that the present claims are patentable over the art of record, and reconsideration of the application and allowance of the claims are respectfully requested.

The Commissioner is authorized to charge any necessary fees or credit any overpayment to Deposit Account No. 13-0017 in the name of McAndrews, Held & Malloy, Ltd.

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Respectfully submitted,

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